

Remarks/Arguments

Amendments to the Specification

Sequence identifiers have been introduced in the paragraph describing Figure 11 on page 7, lines 18-21. Additionally, certain misspellings and misidentification have been corrected in the paragraph on page 35, line 17 - page 37, line 5 and in the paragraph on page 36, line 19 – page 37, line 9. Finally, the sequence of SEQ ID NO:15 has been corrected in the paragraph on page 36, line 19 – page 37, line 9. Applicant submits that no new material is being added to the specification by the present amendments.

Amendments to the Claims

Claim 1 has been amended to recite that the second vector element is “selected from a group consisting of replication elements, vector detection elements, expression elements, gene fusion elements, protein fusion elements, polylinker elements, and combinations thereof.” Support for this amendment is found on pages 12-21 of the specification, describing each of these elements in detail, and in original claim 7.

Drawings

Applicant hereby submits corrected formal drawings and asserts that the corrected drawings are now in compliance with 37 CFR 1.121(d).

Sequence Compliance

In order to comply with the sequence listing requirements of 37 C.F.R. 1.821-1.825, the specification has been amended to provide specific sequence identifiers for each sequence listed in the specification and drawings. Specifically, the existing paragraphs on page 7, lines 18-21 and on 36, line 19 – page 37, line 9 have been amended to provide sequence identifiers for the previously identified sequences.

A substitute sequence listing is provided herein which contains corrections to the previous sequence listing. Responsive to the Examiner’s request, a copy of the attached Notice to Comply is attached.

Rejections under 35 U.S.C. §102

Claims 1, 2, 4, 5, 12, and 14-21 are rejected under 35 U.S.C. §102(e) as being anticipated by Harney et al., US Patent No. 6,495,318 (“Harney”). The Examiner contends that Harney teaches a method of preparing a vector, comprising providing at least two collections of nucleic acid molecules, wherein each of the collections comprises alternative vector fragments and wherein each vector fragment in each collection comprises a portion of a vector element. The Examiner further contends that Harney teaches that the vector element portion on each vector fragment cannot provide the vector element function unless it is joined with its partner vector element portion on another vector fragment. According to the Examiner, this second vector element may be a restriction site.

As an initial matter, Applicant disagrees that one of ordinary skill in the art would consider a single restriction site to be a “vector element”. Nevertheless, solely in order to put the application in condition for allowance, claim 1 has been amended to recite that the vector element is an element selected from the group consisting of replication elements, vector detection elements, expression elements, gene fusion elements, protein fusion elements, polylinker elements, and combinations thereof. Support for this amendment is found on pages 12-21 of the specification, describing each of these elements in detail, and in original claim 7.

Although Harney discloses that vector fragments of each collection may comprise complete vector elements (see e.g., Figure 1 of Harney), Harney neither teaches nor suggests that the vector fragments may comprise portions of a vector element that is selected from a group consisting of these recited vector elements, which vector element portions must be joined to reconstitute the vector element function, as recited in claim 1. Since all pending claims depend from claim 1, Applicant submits that Harney does not anticipate any of the currently pending claims.

Applicant thus respectfully requests that the Examiner withdraw this rejection.

Rejections under 35 U.S.C. §103

Claims 1-5 and 12-21 have been rejected under 35 U.S.C. §103 as being obvious over Harney in view of Jarrell, US Patent No. 5,498,531 ("Jarrell I") or Jarrell, US Patent No. 5,780,272 ("Jarrell II").

The Examiner asserts that the difference between Harney and the currently pending claims is that the nucleic acid molecules of the currently pending claims contain at least one intronic element that is characterized by an ability to trans-splice with a compatible intronic element on at least one of the other molecules. The Examiner asserts that it would have been obvious to add intronic elements to the nucleic acid molecules, such that trans-splicing can take place between them, in order to efficiently manipulate the nucleic acid molecules by specific cleavage and ligation.

First, Applicant points out that only dependent claims 3, 4 and 13 recite vector fragments that are capable of trans-splicing when the vector fragments either comprise RNA or can be transcribed into RNA. Hence, the rejection of claims 1, 2, 12 and 14-21, which do not recite vector fragments that are capable of trans-splicing, is improper based on this combination of references.

Furthermore, Applicant submits that the difference between Harney and those claims that do recite trans-splicing capability is not merely that Harney fails to teach intronic elements, as the Examiner suggests. For the reason discussed above, claim 1 has been amended to recite that the vector element is an element selected from the group consisting of replication elements, vector detection elements, expression elements, gene fusion elements, protein fusion elements, polylinker elements, and combinations thereof. Harney neither teaches nor suggests that the vector fragments may comprise portions of a vector element that is selected from a group consisting of these recited vector elements, which vector element portions must be joined to reconstitute the vector element function, as recited in claim 1. Neither Jarrell I nor Jarrell II cures this deficiency. Thus, the rejection under 35 U.S.C. §103 based on this combination of references should be removed.

Finally, Applicant points out that even if Harney, Jarrell I and Jarrell II, in combination, teach each and every element of the claimed invention (which, for the reasons discussed above, they do not), the Examiner has, in this office action, inappropriately relied on the presumed skill level of one of ordinary skill in the art to establish a *prima facie* case of obviousness. The

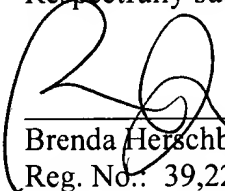
Examiner asserts that "one of ordinary skill in the art would have recognized that the vector fragments of Harney could have been modified to take advantage of the ability of intronic elements to trans-splice with each other as taught be Jarrell... since Jarrell contains teaching which are applicable to any vector fragments desired to be combined."

Regardless of the level of skill in the art presumed by the Examiner, it is well-established in both Federal case law and Patent Office patent examination guidelines that the level of skill in the art cannot be relied upon to provide the required suggestion to combine references. See Manual of Patent Examining Procedure, ch. 2143.01, Section IV (citing Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999)). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See Manual of Patent Examining Procedure, ch. 2143.01, Section III (citing In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)). The Examiner has indicated no such suggestion in any of the cited references. Thus, any rejection under 35 U.S.C. §103 based on this combination of references should be removed.

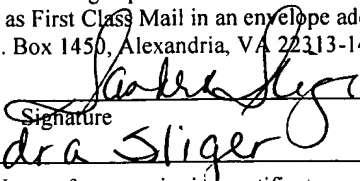
In light of these Remarks and Amendments, Applicant submits that the present application is in condition for allowance. A notice to that effect is respectfully requested.

Please charge any fees associated with this response, or apply any credits, to our Deposit Account Number 03-1721.

Respectfully submitted,


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